

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 100mg/ml SC Oral Suspension for Cattle and Sheep
Albendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of Albendazole, 2 mg of Methyl Parahydroxybenzoate, 0.2 mg of Propyl Parahydroxybenzoate, 3.6 mg of Sodium Selenite Pentahydrate (equivalent to 1.08 mg of Selenium), and 12.052 mg of Cobalt Sulphate Heptahydrate (equivalent to 2.52 mg of Cobalt).

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

1, 2.5, 5 and 10L

5. TARGET SPECIES

Cattle and Sheep

6. INDICATIONS

A broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs, thus reducing pasture contamination
In cattle the product is active against the following species:
Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*,
Lungworms: *Dictyocaulus viviparus*,
Tapeworms: *Moniezia* spp.,
Adult liver fluke: *Fasciola hepatica*

In sheep, the product is active against benzimidazole-susceptible strains of the

following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, (including *N.*

battus), *Chabertia* and *Oesophagostomum*.

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filaria*,

Tapeworms: *Moniezia spp.*,

Adult liver fluke: *Fasciola hepatica*

7. METHOD AND ROUTES OF ADMINISTRATION

For oral administration only, using properly calibrated dosing equipment. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing. One ml contains 100mg albendazole. Shake the container well before use.

Cattle:

Worm dose: 7.5 mg albendazole per kg bodyweight. (3.75 ml Tramazole 10% S&C per 50 kg bodyweight)

Fluke and Worm Dose: 10 mg albendazole per kg bodyweight (5 ml Tramazole 10% S&C per 50 kg bodyweight)

Sheep:

Worm Dose: 5 mg albendazole per kg bodyweight. (1 ml Tramazole 10% S&C per 20 kg bodyweight)

Fluke and Worm Dose: 7.5 mg albendazole per kg bodyweight. (1.5 ml Tramazole 10% S&C per 20 kg bodyweight)

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle

Meat and offal: 14 days

Milk: 60 hours

Sheep

Meat and offal: 4 days

Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNINGS

Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Special warnings/precautions for use

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

This product does not require any special temperature storage conditions
Protect from light

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tulivin Laboratories Ltd
35 Abbeydale Park
Newtownards
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11810/4011

POM-VPS

17. MANUFACTURER'S BATCH NUMBER

BN

A. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Tramazole 100mg/ml SC Oral Suspension for Cattle and Sheep

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Tulivin Laboratories Ltd
35 Abbeydale Park
Newtownards
Co. Down
Northern Ireland

Manufacturer responsible for batch release:

Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 100mg/ml SC Oral Suspension for Cattle and Sheep
Albendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains 100 mg of Albendazole, 2 mg of Methyl Parahydroxybenzoate, 0.2 mg of Propyl Parahydroxybenzoate, 3.6 mg of Sodium Selenite Pentahydrate (equivalent to 1.08 mg of Selenium), and 12.052 mg of Cobalt Sulphate Heptahydrate (equivalent to 2.52 mg of Cobalt).

A pale blue aqueous suspension.

4. INDICATIONS

A broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs, thus reducing pasture contamination.

In cattle the product is active against the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*,

Oesophagostomum, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*,
Lungworms: *Dictyocaulus viviparus*,
Tapeworms: *Moniezia* spp.,
Adult liver fluke: *Fasciola hepatica*

In sheep, the product is active against benzimidazole-susceptible strains of the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, (including *N. battus*), *Chabertia* and *Oesophagostomum*.

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filaria*,

Tapeworms: *Moniezia* spp.,

Adult liver fluke: *Fasciola hepatica*

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and Sheep

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For oral administration only, using properly calibrated dosing equipment.
One ml contains 100mg albendazole.

Cattle:

Worm dose: 7.5 mg albendazole per kg bodyweight. (7.5 ml Tramazole 10% S&C per 100 kg bodyweight)

Fluke and Worm Dose: 10 mg albendazole per kg bodyweight (10 ml Tramazole 10% S&C per 100 kg bodyweight)

Sheep:

Worm Dose: 5 mg albendazole per kg bodyweight. (1 ml Tramazole 10% S&C per 20 kg bodyweight)

Fluke and Worm Dose: 7.5 mg albendazole per kg bodyweight.
(1.5 ml Tramazole 10% S&C per 20 kg bodyweight)

9. ADVICE ON CORRECT ADMINISTRATION

Shake container well before use.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

Do not administer other cobalt and selenium supplements unless specifically advised by your veterinary surgeon

10. WITHDRAWAL PERIOD

Cattle

Meat and offal: 14 days

Milk: 60 hours

Sheep

Meat and offal: 4 days

Do not use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month

12. SPECIAL WARNINGS

Special warnings for each target species

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after infection.

Selenium bioavailability is enhanced in lambs receiving ionophores, so concurrent treatment will increase the risk of toxicity.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles (which includes albendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including in Europe. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in developed countries such as New Zealand. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use in animals

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep. Not to be diluted or mixed with other products. Avoid the introduction of contamination during use. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk dosing programmes should be discussed with your veterinary surgeon. The product should only be used in areas where cobalt and selenium deficiencies are known to occur. If in doubt, consult a veterinary surgeon.

User Warnings

- This product can cause skin and eye irritation.
- Personal protective equipment consisting of suitable protective clothing, including impermeable rubber gloves, should be worn when handling the product.
- In case of accidental spillage onto skin, wash the affected area with soap and water. If irritation persists seek medical advice immediately and show the package leaflet or the label to the physician.
- In case of accidental eye exposure, flush eye thoroughly with running water. If irritation persists seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Pregnancy:

Do not dose ewes at the “fluke and worm” dose rate, (7.5 mg/kg) during tupping or for 1 month after removing the rams.

Lactation:

Can be safely used during lactation

Fertility:

The use in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance

Interaction with other medicinal products and other forms of interaction

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the stated dose.

Incompatibilities

None known

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

DANGEROUS to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2021

15. OTHER INFORMATION

Selenium and Cobalt are included in Tramazole 100mg/ml SC Oral Suspension for Cattle and Sheep as nutritional supplements and are not intended to be used therapeutically.

Pack sizes: 1, 2.5, 5 and 10L
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only

POM-VPS

Revised: October 2021
AN: 02288/2020

Approved: 27/10/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end of the name.